

**REMARKS**

Claims 1-11 and 13-74 are pending after entry of the present amendment. Claims 1-13 were examined in the Office Action dated February 23, 2007.

Claim 1 has been amended to include the subject matter recited in original claim 12, and claim 12 has been cancelled in favor of claim 1. Claim 13 has been amended to read as an independent claim which includes the claim language recited in original claim 1. Support for the present amendments is found throughout the specification and in the originally-filed claims. New claims 65-74 are added by the present amendment and are supported throughout the specification, including by original claims 2-11. No new matter is added by the present amendments.

**Confirmation of Response to Election Requirement**

Applicants hereby confirm the election with traverse to prosecute Group I claims 1-13. Claims 14-64 have been withdrawn from further consideration by the examiner as being drawn to a non-elected invention. Applicants renew their request for rejoinder of claims 14-64 on the basis that the search and examination for those claims would not constitute an undue burden.

In particular, Group III claims 27-42 and 63-64 are appropriate for rejoinder as those claims include the step of applying tension to an implant during one or more of the other steps recited in the claims. As discussed above, Group I claim 1 has been amended to include the subject matter of Group I claim 12, which recited the step of applying tension to the soft tissue at least during part of step (b).

**Oath / Declaration**

The Office Action of February 23, 2007 states that the oath or declaration is defective. According to the Office Action, the oath and declaration is defective because it does not identify the mailing address or the city and either state or foreign country residence of each inventor.

Applicants submit that the declaration is not defective, but rather than an Application Data Sheet should be submitted. The declaration submitted in this case is Form PTO/SB/01A, which is a declaration for an application using an Application Data Sheet. The Office Action of February 23, 2007, cited MPEP §§602.01 and 602.02, which state that the mailing address and residence information may be provided on an application data sheet. Accordingly, an Application Data Sheet is filed herewith, identifying the mailing address and the city and state of residence of each inventor.

### **Claim Rejections - 35 USC § 102**

Claims 1-5, 7-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Mills (WO 00/29037). Mills '037 is owned by the assignee of the present application, Regeneration Technologies, Inc. Mills '037 is a PCT application claiming priority to three US applications: Application No. 09/191,232; Application No. 09/378,527; and Application No. 09/390,174.

In view of the Office Action's determination that claims 1-5 and 7-11 are disclosed in Mills '037, the subject matter of original claims 1-5 and 7-11 will be pursued in one or more continuing applications claiming priority from one or more of Application No. 09/191,232; Application No. 09/378,527; and Application No. 09/390,174.

### **Claim Rejections - 35 USC § 103**

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037). The Office Action acknowledged that Mills '037 does not specifically teach that the implant contains an amount of alcohol in the implant before carrying out step (b) as recited in claim 6. However, the Office Action asserted that it would have been obvious to one of ordinary skill in this art that the alcohol remains in the implant after the treatment in which the implant is contacted with an alcohol. The Office Action stated that Mills '037 does not disclose that the alcohol is removed to waste before carrying out step (b), and that the only fluid removal step mentioned by Mills is after step 4 in Table I.

Applicants submit that the Office Action is incorrect that the only fluid removal step mentioned by Mills '037 is after step 4 in Table I. Mills '037 teaches that the cleaning fluid can be removed after any of steps 1, 2, 3 and/or 4 in Table I. Just before Table I, Mills '037 states "Deep tissue interpenetration by cleaning solutions is achieved by oscillating the pressure in the chamber while adding and **removing** various cleaning solutions." (page 17, lines 14-15 (emphasis added).) Mills '037 discloses that the cleaning solutions in each steps 1, 2, 3 and 4 in Table I can be added and removed. Accordingly, the Office Action has failed to establish that it would have been obvious to one of ordinary skill in the art that the alcohol would remain in the implant after the implant was contacted with an alcohol as in Table I of Mills '037.

Claims 12-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Cook (US 6206931). The Office Action stated that Mills '037 fails to teach that the sterilizing process for treating an implant also comprises applying tension to the soft tissue at least during part of step (b) or during each of steps (a)-(c). However, the Office Action relied on Cook '931 for its disclosure that an implant tissue can be conditioned by the prolonged application of a load on the longitudinal axis or preconditioned by stretching in the lateral dimension.

The Office Action stated that Cook '931 "appears to disclose that the tensioning step occurs after the disinfection steps." (page 12.) Nonetheless, the Office Action concluded that it would have been obvious to provide the tensioning step either before, during or after the disinfection process of a soft tissue in order to obtain a properly conditioned/tensioned connective tissue graft to implant in a patient. The Office Action asserted that it was well known in the art at the time of invention to tension a graft before the actual implantation in order to improve the implant's performance in the patient after surgery.

Applicants submit that the Office Action is incorrect that Cook '931 would have rendered it obvious to apply tension or kinematic restraint to an implant during any of steps (a), (b) or (c) recited in claims 1 or 13. Cook '931 does not disclose or suggest a tensioning step during a disinfection process. To the contrary, Cook '931 discloses

stretching of the implant for preconditioning the implant for tendon and ligament replacement applications. (col. 11, lines 62-64.) Such preconditioning or stretching of these types of implant before implantation is not uncommon, but it does not teach or suggest that tension should be applied to an implant comprising soft tissue during disinfection of the graft. Cook '931 does not disclose any relationship between this preconditioning and the disinfection process.

There is no reason why a disinfection process would have been modified to apply tension while during contact with an oxidizing sterilant, and there are reasons why one would not do so based on the teachings of Cook '931. It would be less convenient to apply tension or stretching **during** a disinfection process (when the implant is immersed, submersed or showered in a liquid medium containing the disinfecting agent – see Cook '931, col. 6, lines 61-67) than **separate from** a disinfection process (as Cook '931 teaches). Also, Cook '931 teaches that its implant is subjected to a disinfection process employing an oxidizing agent, but Cook says nothing about applying tension during the period when the implant is in contact with the oxidizing agent. This is another indication that it was not obvious to apply tension to an implant while it was in contact with an oxidizing agent.

Claims 1 and 13 are independent claims reciting processes for making an implant more suitable for implantation into a recipient. Claim 1 recites (among other things) the step of applying tension to the soft tissue at least during part of step (b), which is contacting the implant with an oxidizing sterilant. Claim 13 recites (among other things) applying kinematic restraint to the soft tissue during each of steps (a), (b) and (c). Those steps involve contacting the implant with a protective agent, an oxidizing sterilant; and a rinsing fluid, respectively. In claims 1 and 13, tension or kinematic restraint is applied to a soft tissue **during** the period when an implant comprising that soft tissue is contacted with an oxidizing sterilant (or other fluid in claim 13).

The present application describes one of the unexpected benefits of including a tensioning step in a process: "Moreover, it has surprisingly been found that less damage arises from contact with a peroxide when tension is applied to a soft tissue than

when no tension is applied, as in conventional methods." (Specification, paragraph 53). Nothing in Cook '931 hints or suggests that tension or kinematic restraint could or should be applied during an implant's contact with a peroxide.

The Office Action identifies several purported reasons for including a tensioning step. (Office Action, page 12, line 12 to page 13, line 2.) None of those reasons would lead a person of ordinary skill to include a tensioning step **during** a disinfection process rather than **separately from** such a process. In *KSR Int'l. Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), the U.S. Supreme Court stated that it is important to identify a reason that would have prompted a person of ordinary skill to combine the prior art elements to arrive at the claimed subject matter. The May 3, 2007 Memorandum from the Deputy Commission for Patent Operations (Margaret A. Focarino) to the Technology Center Directors confirms this: "Therefore, in formulating a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements **in the manner claimed.**" (copy enclosed; emphasis added).

Applicants submit that the Office Action does not provide any legitimate reason why Mills '037 and Cook '931 would be combined to arrive at the subject matter of claim 1 and 13. The Office Action provides no reason why one of ordinary skill in the art would have modified any process disclosed in Mills '037 or Cook '931 to include the step of applying tension or kinematic restraint to a soft tissue while the implant comprising that soft tissue was in contact with an oxidizing sterilant or other fluid.

### CONCLUSION

For the foregoing reasons, Applicants submit that claims 1-11, 13 and 65-74 are in condition for allowance. Applicants also request rejoinder of the non-elected claims.

The Examiner is invited to telephone Applicants' representative to discuss any questions or if Applicants' representative may be of any assistance to the Examiner in the reconsideration and allowance of this case.

The Commissioner is authorized to charge any necessary fees to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

Respectfully submitted,



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